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Research Article

A CLINICAL STUDY TO EVALUATE THE COMBINED EFFECT OF *KESHARSIDDHA GHRIT NASYA* AND *YOG BASTI* ALONG WITH TAB. *PATHYADI GHANVATI* IN *ARDHAVBHEDAKA* W.S.R. TO MIGRAINE

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ABSTRACT

Migraine is the disease of recurrent attack of headache which usually involves half of head. It is felt as throbbing type of pain and associated with various symptoms like, Nausea, vomiting, Photophobia etc. Its acute attacks are treated with different analgesics or ergotamine preparations. A modern medicine gives instant relief from symptoms but may cause drowsiness, insomnia, depression etc.

As compare to that, Ayurveda has variety of natural plant medication and *Panchakarma* therapeutic procedures in management of *Ardhavabhedaka.* Thus, the study was selected to evaluate the efficacy of Ayurvedic *Panchakarma* therapy in migraine. The duration of the treatment was 30 days. Out of 17 migraine patients who were offered this Ayurvedic treatment, 12 patients completed total 30 days treatment protocol. Detail history and examination of each patient were done. *Kesharsiddhaghrit Nasya* and *Dashmul kwath yog basti* given along with Tab. *Pathathyadi Ghanvati*.

Evaluation was done. Total disappearance of headache and associated symptoms at completion of treatment was observed in 66.66% patients. Mild episode of headache without need of any regular treatment was observed in 8.33% of patients. Low intensity of pain along with their regular treatment was observed in 16.66% of patients. Very mild improvement in 8.33% patients and no worst pain was noted in a single patient during treatment (0.0%); respectively. From the results and observation obtained from this study it can be concluded that Ayurvedic Panchakarma therapy showing better results in *Ardhavabhedaka*. No any harmful side effects were found during this entire study.

KEYWORDS: *Ardhavbhedaka*, Migraine, *Nasya*, *Basti, Kesharsiddhaghrit Nasya, Dashmul kwath yog basti, Pathathyadi Ghanvati.*

INTRODUCTION

The term "migraine" refers to a syndrome of vascular pathology of the cranial blood vessels and is one of the commonest headaches encountered in clinical practice. It has a one-year prevalence of 15-18% worldwide [1] affecting around one in every five women. It is frequently incapacitating headache disorder characterized by episodic attack of moderate to severe headache felt as throbbing pain on one side of head and associated with various symptoms like, Nausea, vomiting Photophobia etc., or sensitivity to movement, visual, auditory, and other afferents inputs.[3] Some are associated with conspicuous sensory, motor and mood disturbances. Changes in neurotransmitters levels within the brain are thought to play a role in migraine headache. Migraine is most common cause of headache afflicts approximately 15% of women and 6% of men.[4] About 60% of patients with headache have tension type headache, 35% have migraine and 5% have cluster headache. According to ICHD (International classification of headache disorder) migraine constitute 16% of primary headache and affects 10-20% of general population.

Where in these, symptoms almost replicate with condition of *Ardhavbhedaka*, which is one among the 11 types of *Shirorogas* explained in classical text of Ayurveda's which presents with *Bhedtodavatardhaparshwa Shirahshul* having periodic attack(5) with *Prakash* and *Shabdaa-sahishnuta*. Clinically, it is *Tridosh* dominant disease[6] and *Acharya Charaka* stated that the vitiated *Doshas* after reaching *Shirah* vitiates *Rakta* to produce *Shiro Roga* (headache). Its diagnosis is based on mainly

clinical history. Prevalence of migraine significantly increases due to various triggering factors and most of the trigger factor are related with dietary items, daily routine, environmental factor, stress, awakening during night time due to night duties and sleeping in day time etc. Irregular life style plays significant role in precipitation of migraine. Now a days, lots of changes taken place in life style, social and religion custom and manners has an impact on *Tridoshas*. This is predisposing factors of *Ardhavbhedaka*.

A modern medicine shows instant relief from symptoms but may cause drowsiness, insomnia, depression etc, and also leads to drug dependency. In compare to that Ayurveda has a many type of natural medication and *Panchakarma* procedures in the treatment of *Ardhavabhedaka* and also Ayurvedic treatment shows notable result in reducing the frequency, intensity of pain and associated symptoms in the migraine patient. Thus, here an attempt has been made to evaluate the efficacy of *Nasya* and *basti karma* along with tab. *Pathyadi Ghanvati* in migraine. *Nasya* is the procedure in which medicine (Herbal oils or liquid) are administered through the nostrils in order to purify head and neck region. Therapy cleanses and opens the channels of head, through the mucous membrane along with its microvascular structures. Thereby improving the process of oxygenation which has direct influence on the functioning of brain to control all *Doshas* in head region and become helpful in treatment of migraine. *Basti* is most effective treatment of *Vata* disorders. *Shool* caused due to all *Doshas* but *Vata* is main factor and it is root cause of vast majority of diseases so, we can control the *Vatadosha* through the use of *Bastikarma* as a *Shodhana* therapy. *Dashamoola Taila* from *Bhaisajya Ratnavali*[7] used for *Basti karma*, which is having *Vatahara* properties, has been selected in the present study.

RATIONALE OF STUDY

Modern drug therapy provides instant relief from symptoms but it is not for long lasting effect and with side effects, adverse event and contraindications. Therefore there is necessity to think about the evidence based therapy with the help of ancient science.

AIM AND OBJECTIVES OF STUDY

1. To evaluate the combined efficacy of *Kesharsiddha Ghrit nasya* and *Dashmul kwath Yog basti* along with Tab. *Pathyadighanvati* in management of *Ardhavbhedaka* w.s.r. to Migraine.
2. To study the etiopathogenesis of *Ardhavbhedaka* - Migraine from Ayurvedic and modern point of view.

MATERIALS AND METHODS

This clinical study was carried out in patients attended the O.P.D. and I.P.D. of Shalakya Tantra Department, M.A.Podar Hospital, Worli, Mumbai. The patients were selected randomly, who fulfilling the criteria for diagnosis, irrespective of their *Desha*, *Jati*, *Prakriti*, *Satva* etc. The study was conducted in 17 subjects. Patients written informed consent was taken before starting the treatment. Questionnaire is filled up before and after the completion of treatment. Patients were instructed to maintain daily diary. Periodic follow up was taken for 3 months. Assessment was made on the basis of gradation score given to each symptoms ranging from 0-4.

MATERIALS

S.No.	Drug	Content	Dose	Method of administration	Duration
1	*Kesharsiddhaghrita nasya*	*1.Keshar* *2.Ghrit*	4 drops in each nostril	Medicine administered through *nasal* cavity (*Nasal* instillation)	For 7 days
2	*Yog basti*	*1.Dashmula kwath* *2.Til tail*	450ml 60ml	The prepared *Basti* administered through anal route. With the help of enema can Alternate *Anuvasan* and *Asthapan*.	For 14 days
3	*Pathyadi Ghanvati*[8]	*1. Haritaki* *2. Amalaki* *3. Bibhitaki* *4. Haridra* *5. Kiratatikta* *6. Giloy*	2 tablets 2 times a day with lukewarm water	Orally	For 90 days

1. Before starting the treatment *Pachan* was given with *Ampachak vati* 2 BD (before meal) and tab. *Gandharva haritaki* 2 HS, with lukewarm water for 7days.
2. Tab. *Pathyadi ghanvati* 2 BD (after meal.) given with lukewarm water for 3 months.
3. *Nasya Karma* done with *Kesharsiddha ghrit* for 7 days at morning time.

4. After completion *Nasya, basti karma* was done with *Dashmul kwath* and *Tila tail* for 14 days.

Patients those who have in acute migraine attack were instructed to take one tablet paracetamol 500mg. (stat)

Total treatment phase was- 30 days.

Diagnostic criteria

Patients were diagnosed on the basis of subjective criteria of diseases and by using VAS scale.

Inclusion Criteria

1. Patients having sign and symptom of *Ardhavabhedaka* (Migraine) according to Ayurvedic Classics as well as modern science.
2. Individuals of either gender, irrespective to their age.
3. Patients who are willing to follow dietary restrictions.
4. Patient who willing to complete daily diary and take medicine for 90 days.

Exclusion Criteria

1. Secondary headache caused by meningitis, tumor, encephalitis, cervical spondylitis or other neurological causes, patients using any other systemic drugs which may alter the results of study.
2. Marked depression.
3. Anxiety or Psychosis, under psychiatric medications.
4. Major medical illness like SOL and other autoimmune diseases.
5. Pregnancy
6. Clotting disorders.
7. Other types of headaches.
8. Referred pain in half of head due to disorders of ear, eye, teeth, throat etc.
9. Patient with complicated Migraine, hemiplegic migraine etc.
10. Use of other alternative medication during Ayurvedic treatment.

Withdrawal

Subjects withdrawn from study on following grounds-

1. Patients free to withdraw their names from study at any time without giving any reason there off.
2. Failure of subject to adhere the treatment protocol requirement.
3. Any adverse event occurs during therapy.
5. Those who are not responding to treatment and required another drug intervention.

Investigations

CT imaging of head (CT scan)

MRI of head

All Routine

Neck x-ray (if necessary)

Criteria for assessment

Assessment of effect of treatment on sign and symptoms will be done based on subjective parameters by adopting a grading pattern before and after treatment and by using vas scale.

Assessment was done by

The assessment was done by adopting the following scoring pattern for subjective symptoms and with the help of VAS scale

1. Complete Relief: 100% relief in objective and subjective signs and symptoms.
2. Marked improvement: upto 75% relief in objective and subjective signs and symptoms.
3. Moderate improvement: upto 50% relief in objective and subjective signs and symptoms.
4. Mild improvement: upto 25% relief in objective and subjective signs and symptoms.
5. Unchanged: Below 25% relief in objective and subjective signs.

Gradation of Subjective Parameters

S. No	Complaints	Grade
1)	**Headache-Severity of pain**	
	No pain	0
	Pain tolerable	1
	Not Disturbing Routine work	2
	Disturbing Routine work	3
	Intolerable pain	4
2)	**Duration of Headache**	
	Nil	0
	2-3 hrs/day	1
	3-6 hrs/day	2
	6-12hrs/day	3
	>12hrs/day	4

3)	**Frequency of headache**	
	No attack	0
	Once in 30 days	1
	Once in 20 days	2
	Once in 10 days	3
	Continuous/daily	4
4)	**Site for pain**	
	1) *Ardhashir*, 2) *Manya*, 3) *Bhru*, 4) *Shankha*, 5) *Lalat*, 6) *Karna*, 7) *Akshi*	
	Nil	0
	2 out of 7	1
	4 out of 7	2
	6 out of 7	3
	7 out of 7	4
5)	**Other associated complaints**	
	Photophobia- No symptoms	0
	Vertigo- mild (1-3 symptoms)	1
	Weakness- moderate (3-5 symptoms)	2
	Loss of appetite- severe (5-7 symptoms)	3
	Fatigue- Excruciating (force to taken)	4
	Visual aura	

Fallow up phase

Patients were observed for 3 months. While follow up taken at on 7th day, 15th day, 30th day, 60th day and 3 months.

1st follow up on 7th day of treatment.

2nd after completion of *Nasyakarma* i.e., on 15th day.

3rd on 30th day i.e. after completion of *Yogabastikram*.

4th and 5th f/u taken on 2M and 3M.

Advice to Patient

Patient was not allowed to take any other alternative medication.

Eligible patient were instructed to maintain a daily headache diary after start and completion of treatment.

Adverse event should be recorded and mention its characteristics.

Advised to take minimum 8 hrs sleep.

Abstention from smoking and drinking.

Statistical Estimation of Results

Obtained data were analyzed statistically. The values were expressed as percentage of relief and Standard Error Mean. The data were analyzed by test was applied for-

Descriptive statistics like frequencies and percentage for categorical data, Mean and SD for numerical data has been depicted.

Intra group comparison was done using Friedman's (for >2 observations) followed by pair wise comparison using Wilcoxon Signed rank test.

Comparison of frequencies of categories of variables with groups was done using chi square test.

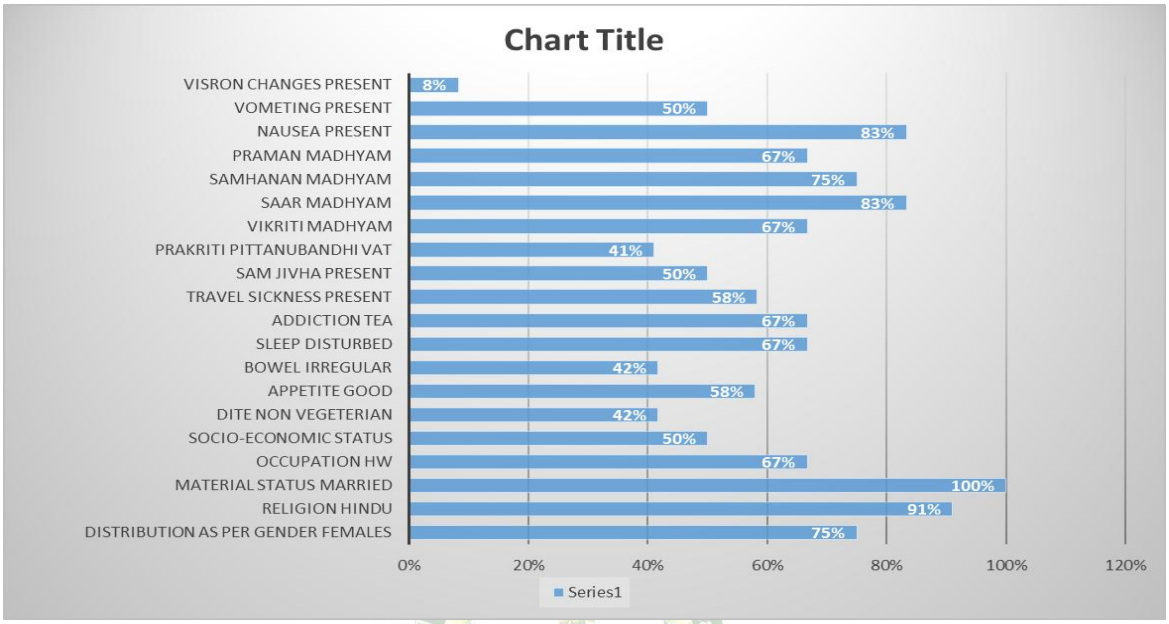
For all the statistical tests, $p<0.05$ was considered to be statistically significant, keeping α error at 5% and β error at 20%, thus giving a power to the study as 80%.

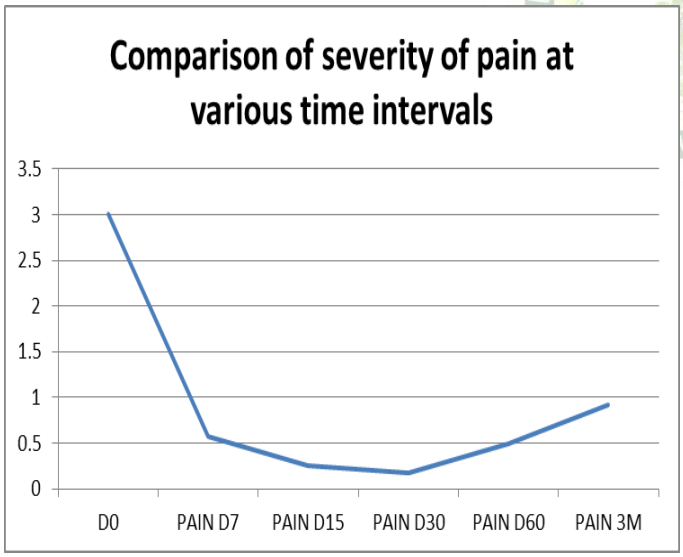
OBSERVATION AND RESULTS

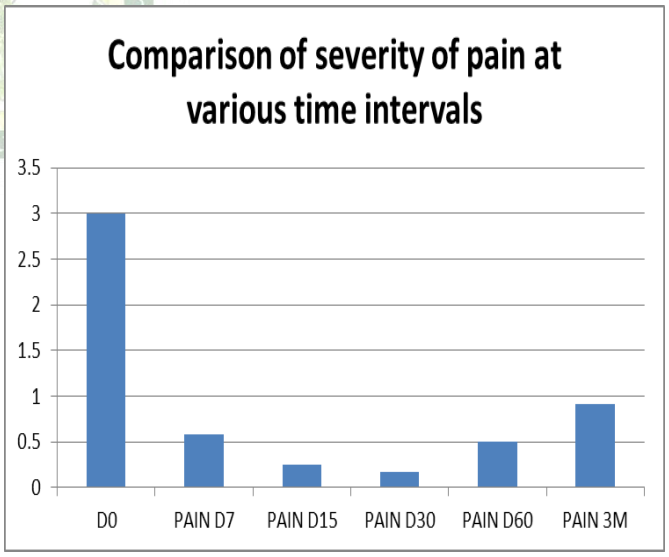
In this clinical trial of *Ardhavbhedaka* total 17 patients were registered out of which 12 patients were completed total treatment protocol. 5 patients quit the treatment at various levels. Hence the observation was carried out on remaining 12 patients. In this present clinical trial maximum number of patients i.e. 75% belongs to 30-40 age group with majority of female subject's i.e. 75% and majority of them were housewives. Majority of patients were belongs to middle class, majority of patients had the chronicity between 2-10 years. Majority of patient were *Vata* Pitta *Prakriti*, majority of patients were taken *Amla*, *Katu* or *Madhurarasa* and a non-vegetarian diet. Majority of patients had good appetite and regular bowel. 66.7% patients had disturbed sleep during migraine headache. 66.7% patients were addicted for tea. 58.3% patient had travel sickness. Majority of patients had *Vishamaashan*.

Majority of patients had h/o day sleeping and night awakening, exposure to sunlight, *Chinta* and *Krodh* etc. *Mutra*, *Druk*, *Sparsha* and *Shabd* in all patient were normal, 41.7% patient had *Asamyak mala* rest patients had normal *Mala pravruti*. 50% patients had *Asamyakajivha*. Majority of patients had

Madhyam and *Krusha akruti*. Majority of patients i.e. 83.3% had *Madhyam*, *Sara*, *Samhanan*, 83.3% patients had h/o nausea and 50% patients experienced vomiting during attack of headache. Vision changes during episodes of headache were observed in only one patient. Mental confusion and imbalance were absent in all patients. Sensitivity to light was observed in 75% of patients and appetite changes in 58.3%. Result was analyzed individually and overall assessment was done on the basis of previous mentioned criteria. The parameters of the study were severity of pain, duration of pain, frequency of pain, site of pain and other associated complaints as mentioned in assessment scale, vas scale also used to note the severity of migraine headache.







Chief Complaints

Severity of pain

Before starting the treatment 2 patients had intolerable pain, 8 patients had pain which disturbing their routine work, 2 patients had pain which does not disturbing routine work. After completion of treatment 8 patient had not experienced any type of pain (i.e. total free from pain). One patient had pain which was not disturbing his/her routine work. 3 patients had mild pain which is tolerable. No one had experienced severe pain or intolerable after completion of treatment.

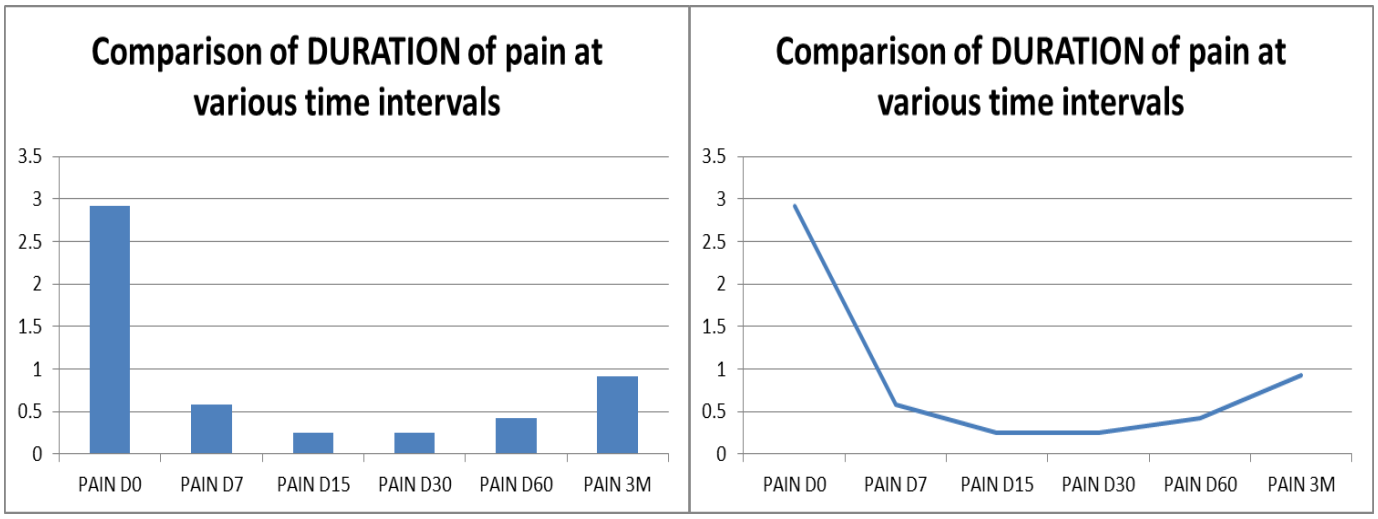
Comparison of severity of pain at various time intervals

	N	Mean	Std. Deviation	Minimum	Maximum	Median	Mean Rank	Chi square value	p value of Friedman Test
D0	12	3.00	.603	2	4	3.00	5.96		
Pain D7	12	.58	1.240	0	4	.00	3.00		
Pain D15	12	.25	.622	0	2	.00	2.71	42.439	0.000**
Pain D30	12	.17	.389	0	1	.00	2.42		
Pain D60	12	.50	.905	0	3	.00	3.00		
Pain 3M	12	.92	.996	0	3	1.00	3.92		

There was a statistically significant / highly significant difference was seen for the values between the time intervals (p<0.01, 0.05) with higher values at D0 and least at D30.

Duration of pain

Before starting of the treatment 4 patients had duration of pain over 12 hrs/day, 2 patients had pain in between 6-12 hrs/day, 6 patients had pain between 3-6 hrs/day, after completion of treatment duration of pain was completely reduced in 8 patients. 2 patients had mild pain i.e. In between 2-3 hrs and one had mild pain i.e. for 3-6 hrs/day. 1 patient had no change in duration of pain and (the result on severity of pain showed highly statistically significance with p value p 0.000).



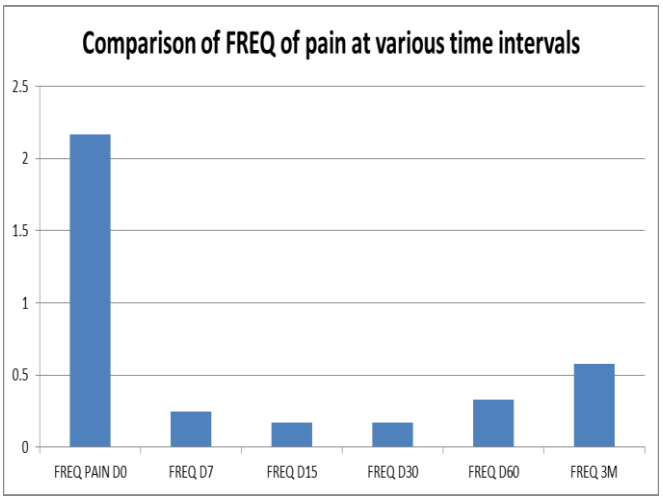
Comparison of duration of pain at various time intervals

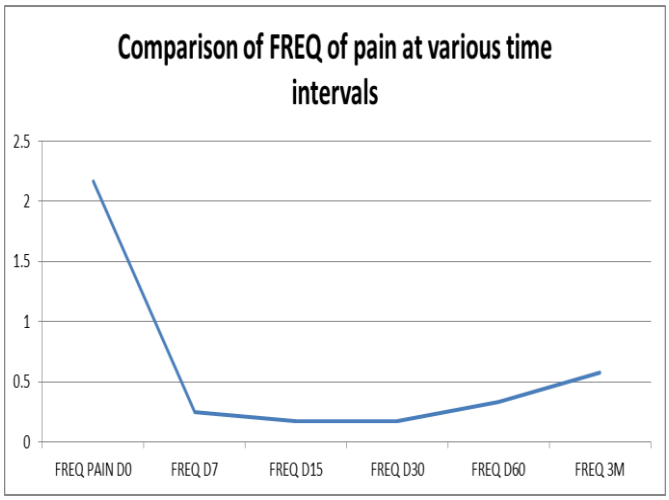
	N	Mean	Std. Deviation	Minimum	Maximum	Median	Mean Rank	Chi square value	p value of Friedman Test
Pain D0	12	2.92	.900	2	4	3.00	5.96		
Pain D7	12	.58	1.240	0	4	.00	3.00		
Pain D15	12	.25	.622	0	2	.00	2.63	41.926	0.000**
Pain D30	12	.25	.452	0	1	.00	2.54		
Pain D60	12	.42	.669	0	2	.00	2.88		
Pain 3M	12	.92	.900	0	3	1.00	4.00		

There was a statistically significant / highly significant difference seen for the values between the time intervals (p<0.01, 0.05) with higher values at D0 and least at D15, 30.

Frequency of attack

Before treatment 1 patient had frequency of attack which is daily /continuous. 3 patients had frequency of attack once in 10 days, 6 patients had frequency of attack once in 20 days, 2 patients had frequency of attack once in 30 days. After treatment 8 patients did not experience frequency of attack, 3 patients had frequency of attack once in 30 days were observed, 1 patient had frequency of attack 2 times in 30 days. The result on severity of pain showed highly statistically significance with p value p 0.000. Complete relief in severity of pain, duration and frequency of attack was observed in 66.6% and 33.4% patients had markedly reduced their severity of pain, duration and frequency of attack respectively.





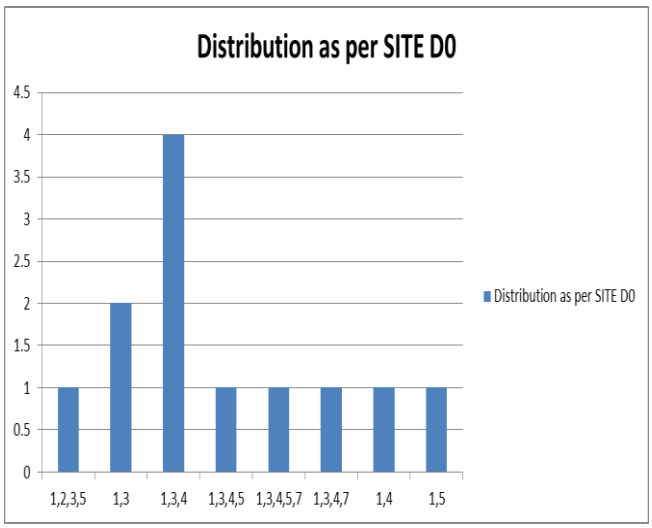
Comparison of frequency of pain at various time intervals

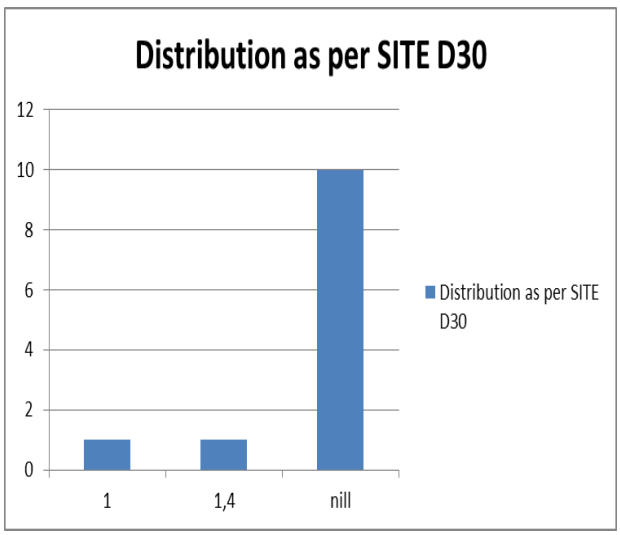
	N	Mean	Std. Deviation	Minimum	Maximum	Median	Mean Rank	Chi square value	p value of Friedman Test
Freq Pain D0	12	2.17	.718	1	3	2.00	6.00		
FREQ D7	12	.25	.452	0	1	.00	2.88		
FREQ D15	12	.17	.389	0	1	.00	2.67	45.673	0.000**
FREQ D30	12	.17	.389	0	1	.00	2.67		
FREQ D60	12	.33	.492	0	1	.00	3.08		
FREQ 3M	12	.58	.515	0	1	1.00	3.71		

There was a statistically significant / highly significant difference seen for the values between the time intervals ($p<0.01, 0.05$) with higher values at D0 and least at D15, 30.

Site of pain

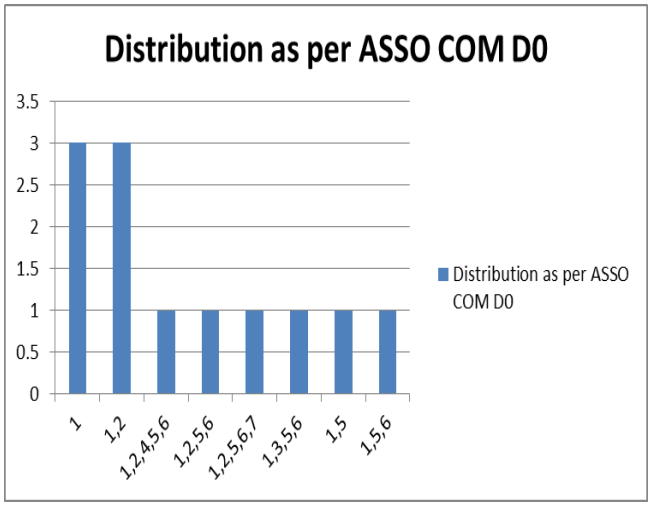
Site of pain on day zero in 4 patients i.e., (33.3%) was- *Ardhashir*, *Bhru* and *Shankha Shirhashula*. 2 patients i.e., (16.7%) had pain at *Ardhashir* and *Bhrupradesh*. Rest of patients in this clinical trial, the site of pain was at *Ardhashir, Bhru, Shankha, Lalat* and *Akshi Pradesh*. On day 30, i.e., after completion of treatment 2 patients had site of pain at *Ardha shir* and *Bhru Pradesh* rest all i.e. 10 patients were free from symptoms so, there were no mild pain at any site.

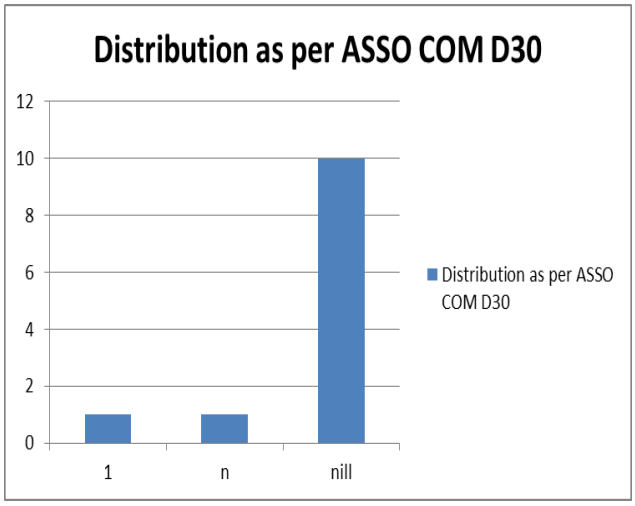




Associated complaints

In this clinical trial majority of patients i.e., more than 50% of patients had nausea and vomiting during episodes of headache. The result on nausea, vomiting, photophobia, vertigo, weakness, fatigue and loss of appetite showed highly statistically significance with p value 0.000.

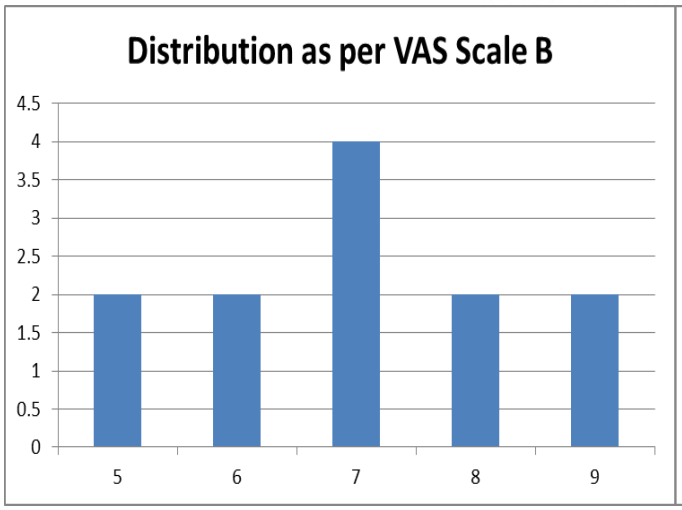


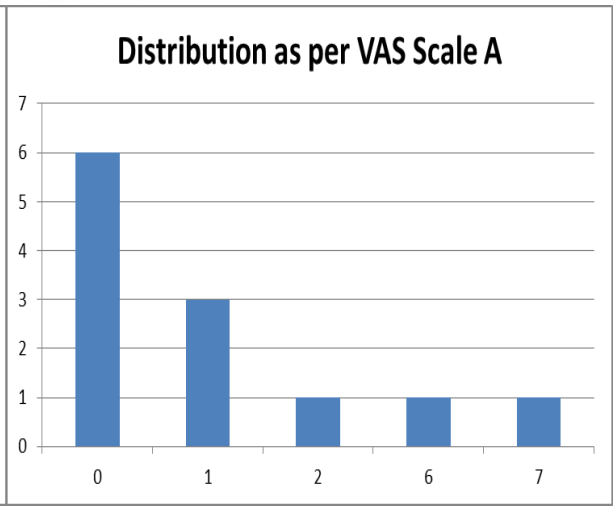


Vas scale measurement

Before starting the treatment 2 patients had 9, 2 had 8, 4 patient had 7, 2 patients had 6, and 2 had 5 VAS measurements. After completion of treatment, it reduced as shown in table below:

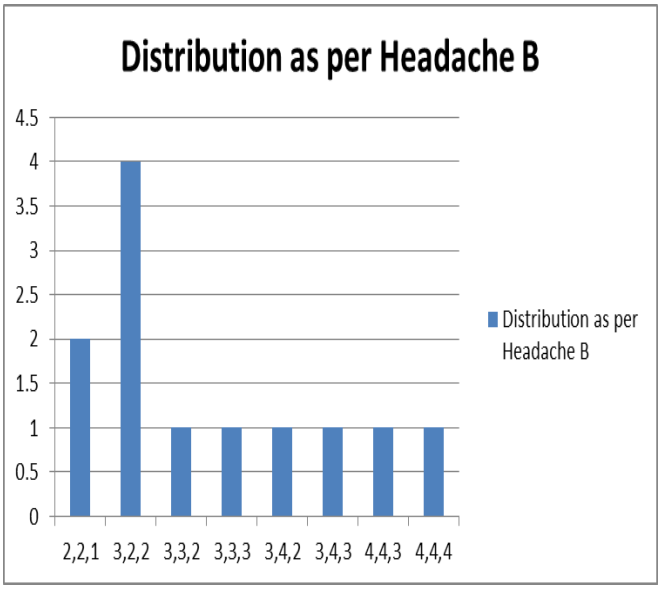
Sr. no	No of patients	percentage	VAS measurement BT	No of patients	percentage	VAS measurement AT
1	2	16.7%	9	1	8.3%	7
2	2	16.7%	8	1	8.3%	6
3	4	33.3%	7	1	8.3%	2
4	2	16.7%	6	3	25%	1
5	2	16.7%	5	6	50%	0

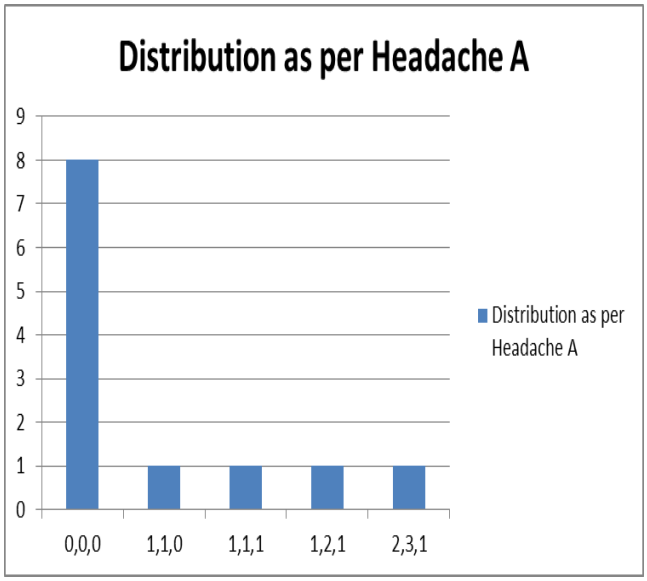




OVERALL ASSESSMENT

Out of 12 patients 8 patients got complete relief followed by 2 patients with marked relief. 1 patient had moderate relief in severity of headache and one had mild improvement in sign and symptoms of migraine headache. The result on overall assessment showed statistically highly significant effect with p value 0.000.





DISSCUSSION

The known cases of migraine were taken from Shalakya OPD. Detail history and complete examination of each patient was done. Ayurvedic treatment i.e., *Kesharsiddhaghritnasya* and *Dashamul-kwath yog basti* given along with tablet *Pathyadi ghanvati.* Assessment was done after completion of treatment. Probable mode of action of *Nasya karma* was- according to Charak Acharya *Nasa* is portal of *Shiras*. The *Keshar siddha ghrit* administered through nose as *Nasya dravya* is reaches to the brain through the *Shringatak marma* which can be correlated with cavernous and intercavernous sinus according to modern point of view. This *Shringatak marma* contain *Siras* which provides the *Santarpan* to all *Urdhvajatrugata* organ. In this way drug spread to *Murdha* through this *Sira*, and helped to eliminate only the morbid *Doshas* (toxic substances) which was responsible for producing the disease.

Keshar siddha medicated *Ghrita* has been selected here to pacify the *Tridosha* mainly *Vata dosha.* It acts as *Srotoshodhaka,* as it is having *Tikta* and *Katu Rasa,* which helps in expelling out the morbid *Doshas* and also having properties like *Kleda Shoshana* and *Shleshma Prashamana* because of *Tikta Rasa.* Probable mode of action of *Basti karma*- *Acharya sushrut* has told that the *Virya* of *basti* drug reaches all over the body through the *Srotas* in the same way that the water poured at the route of the plant reaches up to the leaves. He has further explained that even though *Basti* drugs quickly comes out with *Mala* and their *Virya* acts all over the body by the action of *Apana vayu* and other *Vayu*. The action takes place just like as sun draws moisture from earth. Also *Acharya Parashar* has explained that, *Guda* is the *Mula* of body where all *Sira* are located, the *Basti* drug administered through the *Guda* reaches up to the head and eliminate only the morbid *Doshas* (toxic substances) which is responsible for producing the disease. In this way *Basti karma* helps to reset and maintain the balanced state of *Vatadosha* and helps in treatment of migraine. The action of *Dashmul yogbasti* occurred same as explained above.

Etiopathogenesis of *Ardhavbhedaka* in patient is as follows:

Ruksha ahar sevan, mental stress, night awakening and day sleeping, due to these causative factors

↓

Vitiation of *Tridoshas*

↓

Vitiated *Doshas* gets lodged in half of the head.

↓

Throbbing type of pain occurred at left half of head, *Bhru, Shankha, Lalata* and *Manya Pradesh*

↓

Ardhavbhedaka

As explained above *Nasya* and *Basti karma* breaks this *Samprapti* and becomes helpful in reducing the migraine symptoms.

CONCLUSION

The known cases of migraine were taken. They were diagnosed as per Ayurveda as *Ardhavbhedaka*. *Keshar siddha ghrit nasya* and *Dashmul kwath yog basti* was given to every patient as *Shodhan chikitsa* (elimination therapy) *Pathyadi ghanvati* given as *Shaman chikitsa* i.e., pacifying therapy. Evaluation was done. Total disappearance of headache and associated symptoms at completion of treatment was observed in 66.66% patients. Mild

episode of headache without need of any regular treatment in 8.33% of patients was seen. Low intensity of pain along with their regular treatment 16.66% of patients was seen. Very mild improvement in 8.33% patients and no worst pain was noted in a single patient during treatment (0.0%); respectively. No any adverse drug reaction was found during this entire study. From the results and observation which was obtained from this study it can be concluded that, *Kesharsiddha ghrit nasya* and *Dashmul kwath yog basti* along with tablet *Pathyadi ghanvati* are effective in management of *Ardhavbhedaka*.

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